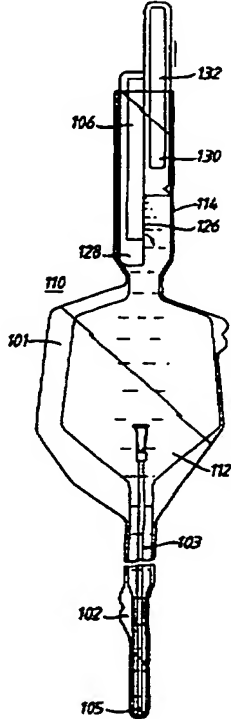


PCTWORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61M 25/01, A61F 5/44		A1	(11) International Publication Number: WO 97/26937
			(43) International Publication Date: 31 July 1997 (31.07.97)
(21) International Application Number: PCT/SE97/00096			(81) Designated States: AL, AM, AT, AT (Utility model), AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DE (Utility model), DK, DK (Utility model), EE, ES, FI, FI (Utility model), GB, GE, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, US, UZ, VN, ARIPO patent (KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).
(22) International Filing Date: 22 January 1997 (22.01.97)			
(30) Priority Data: 9600276-1 25 January 1996 (25.01.96) SE			
(71) Applicant (for all designated States except US): ASTRA AKTIEBOLAG [SE/SE]; S-151 85 Södertälje (SE).			
(72) Inventors; and (75) Inventors/Applicants (for US only): ISRAELSSON, Anette [SE/SE]; Mejerigatan 16, S-412 76 Göteborg (SE). PETTERSSON, Agneta [SE/SE]; Råstengatan 52 C, S-416 54 Göteborg (SE). UTAS, Jan [SE/SE]; Sparvvägen 9, S-434 96 Kungsbacka (SE).			
(74) Agent: ASTRA AKTIEBOLAG; Patent Dept., S-151 85 Södertälje (SE).			Published With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.
(54) Title: HYDROPHILIC URINARY CATHETER HAVING A WATER-CONTAINING SACHET			
(57) Abstract			
<p>A wetting apparatus (110) for wetting a hydrophilic urinary catheter (103) comprises a wetting receptacle (101) which defines a wetting fluid receiving area (102) for receiving the hydrophilic urinary catheter and a hydrophilic urinary catheter wetting fluid container (106) having a discharge outlet (126) movable from a closed position to an open position on application of a predetermined condition thereto to enable the wetting fluid to be discharged from the wetting fluid container. The wetting fluid container provided can be positioned in the wetting receptacle in an operational position in which at least the discharge outlet of the wetting fluid container is disposed within the bounds of the wetting receptacle, the wetting receptacle being so constructed and the wetting fluid container being so disposed relative to the wetting receptacle when in the operational position that application of the predetermined condition to the discharge outlet of the wetting fluid container when in the operational position enables the wetting fluid to be discharged into the wetting fluid receiving area for wetting of the hydrophilic urinary catheter.</p>			
			

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AM	Armenia	GB	United Kingdom	MW	Malawi
AT	Austria	GE	Georgia	MX	Mexico
AU	Australia	GN	Guinea	NE	Niger
BB	Barbados	GR	Greece	NL	Netherlands
BE	Belgium	HU	Hungary	NO	Norway
BF	Burkina Faso	IE	Ireland	NZ	New Zealand
BG	Bulgaria	IT	Italy	PL	Poland
BJ	Benin	JP	Japan	PT	Portugal
BR	Brazil	KE	Kenya	RO	Romania
BY	Belarus	KG	Kyrgyzstan	RU	Russian Federation
CA	Canada	KP	Democratic People's Republic of Korea	SD	Sudan
CF	Central African Republic	KR	Republic of Korea	SE	Sweden
CG	Congo	KZ	Kazakhstan	SG	Singapore
CH	Switzerland	LI	Liechtenstein	SI	Slovenia
CI	Côte d'Ivoire	LK	Sri Lanka	SK	Slovakia
CM	Cameroon	LR	Liberia	SN	Senegal
CN	China	LT	Lithuania	SZ	Swaziland
CS	Czechoslovakia	LU	Luxembourg	TD	Chad
CZ	Czech Republic	LV	Latvia	TG	Togo
DE	Germany	MC	Monaco	TJ	Tajikistan
DK	Denmark	MD	Republic of Moldova	TT	Trinidad and Tobago
EE	Estonia	MG	Madagascar	UA	Ukraine
ES	Spain	ML	Mali	UG	Uganda
FI	Finland	MN	Mongolia	US	United States of America
FR	France	MR	Mauritania	UZ	Uzbekistan
GA	Gabon			VN	Viet Nam

HYDROFILIC URINARY CATHETER HAVING A WATER-CONTAINING SACHET

The present invention relates to wetting apparatus for wetting of hydrophilic urinary catheters comprising a wetting receptacle which defines a wetting fluid receiving area which is adapted to receive a hydrophilic urinary catheter and a hydrophilic urinary catheter wetting fluid container having a discharge outlet movable from a closed position to an open position on application of a predetermined condition thereto to enable the wetting fluid to be discharged from the wetting fluid container into the wetting fluid receiving area for wetting of the hydrophilic urinary catheter. The present invention further relates to a fluid container of a type which may be used in such apparatus.

Intermittent self-catheterisation is widely employed by patients suffering from for example strictures or traumas in the urinary system as well as by paralysed patients to enable the patients to live a nearly normal home life. Urinary catheters supplied for intermittent self-catheterisation in general need to have a lubricant applied to the outer surfaces thereof to facilitate insertion into the urethra. For example, hydrophilic urinary catheters have a hydrophilic outer surface coating which should be wetted by a fluid such as water or saline for a certain time period prior to insertion thereof into the urethra of a patient for lubrication purposes.

Various methods for lubricating urinary catheters have been previously proposed, examples of which are given below.

Prior US patent No. 5209726 makes known a self-lubricating urinary catheter and a method for self-catheterisation. The catheter has an annular lubricant reservoir surrounding an inner tube having perforations. As the catheter is inserted into the urethra of a patient lubricant is forced from the reservoir into the inner tube and out into the urethra through a discharge outlet in the catheter. Lubrication of the outer surface of the catheter therefore only takes place as the catheter is being inserted into the urethra of the patient resulting in at least some initial discomfort for the patient on insertion of the catheter.

Prior US patent No. 3967728 makes known a catheter package comprising a urinary catheter and a rupturable, lubricant containing pouch. One edge of the pouch is located within the package adjacent to the tip of the catheter and the seal at that edge is made so that it ruptures when the pouch is squeezed thereby to lubricate the tip of the catheter. As
5 only the tip of the catheter is lubricated the patient will still suffer discomfort on insertion of the catheter into the urethra.

Prior UK patent application publication No. 2284764 makes known a catheter and urine collection bag assembly comprising (i) a catheter having a shaft with a rounded tip, a
10 drainage aperture in the tip and a flared portion to the rear of the shaft, and (ii) a urine collection bag within which the catheter is disposed and which at a forward end is formable with an aperture which is sufficiently large to permit the tip and shaft of the catheter to pass through but small enough for the flared portion of the catheter to engage therewith to form a mechanical seal against leakage of urine. Once the catheter has been extended through the
15 aperture it is ready to be inserted into the urethra of a patient. Urine is transported rearwardly through the catheter from the bladder of the patient for collection in the urine collection bag. It is disclosed that a separate, burstable container containing a lubricious substance may be included within the urine collection bag for lubricating the catheter. No details are given, however, of the construction of the container nor of the disposition of the
20 container relative to the catheter.

Applicant's prior International patent application publication No. WO86/06284 discloses a wetting and storage device for a hydrophilic urinary catheter. A wetting pocket is provided, closed at one end so that it may be filled with a wetting liquid and a hydrophilic urinary
25 catheter is then introduced into the pocket for wetting thereof. No liquid container, though, is provided in the device for releasing wetting liquid into the pocket immediately prior to use of the catheter. Wetting liquid for the pocket therefore has to be supplied separately by the patient. This is inconvenient because a sterile supply of wetting liquid is not necessarily always on hand to the patient and there is a marked possibility of spillage of
30 the wetting liquid.

The hitherto proposed lubricating apparatus for urinary catheters discussed above have the drawback that they make no or inadequate provision for lubricating hydrophilic urinary catheters. As an example, the lubricating arrangements made known in US patent No. 3967728 and UK patent application publication No. 2284764 are for catheters of non-
5 hydrophilic character, the lubricant therefore being a gel which is unsuited for lubricating a hydrophilic catheter. The prior lubricating apparatus therefore fail to provide an integrated supply of hydrophilic urinary catheter wetting fluid let alone an integrated supply of hydrophilic urinary catheter wetting fluid which on discharge results in wetting of the insertable length or substantially the insertable length of a hydrophilic urinary catheter prior
10 to insertion of the catheter into the urethra of a patient.

Patients using hydrophilic urinary catheters accordingly require improved means for lubricating the catheters. The present invention therefore proposes to address this requirement.

15 According to a first aspect of the invention there is provided a wetting apparatus for wetting a hydrophilic urinary catheter comprising a wetting receptacle which defines a wetting fluid receiving area for receiving a hydrophilic urinary catheter and a hydrophilic urinary catheter wetting fluid container having a discharge outlet movable from a closed position to an open
20 position on application of a predetermined condition thereto to enable the wetting fluid to be discharged from the wetting fluid container, the wetting fluid container being integrated with the wetting receptacle in an operational position in which at least the discharge outlet of the wetting fluid container is disposed within the bounds of the wetting receptacle, the wetting receptacle being so constructed and the wetting fluid container being so disposed
25 relative to the wetting receptacle when in the operational position that application of the predetermined condition to the discharge outlet of the wetting fluid container when in the operational position enables the wetting fluid to be discharged into the wetting fluid receiving area for wetting of the hydrophilic urinary catheter and the wetting fluid receiving area being adapted such that the insertable length or substantially the insertable length of the
30 hydrophilic urinary catheter is wetted by the wetting fluid discharged into the wetting fluid receiving area.

By "integrated" is meant that the wetting fluid container and wetting receptacle are formed into a one-piece unit, that is to say, the wetting fluid container is supported on or by the wetting receptacle.

5

An "on tap" supply of lubricant for the hydrophilic urinary catheter is therefore available to the patient and the problem of possible spillage of the wetting fluid alleviated. Furthermore, an increased comfort on insertion of the catheter into the urethra results due to the insertable length or substantially the insertable length of the catheter being lubricated prior to insertion.

10

According to a second aspect of the invention there is provided a wetting apparatus for wetting a hydrophilic urinary catheter comprising a wetting receptacle which defines a wetting fluid receiving area for receiving a hydrophilic urinary catheter and a hydrophilic urinary catheter wetting fluid container having a discharge outlet movable from a closed position to an open position on application of a predetermined condition thereto to enable the wetting fluid to be discharged from the wetting fluid container, the wetting fluid container being integrable with the wetting receptacle in an operational position in which at least the discharge outlet of the wetting fluid container is disposed within the bounds of the wetting receptacle, the wetting receptacle being so constructed and the wetting fluid container being so disposed relative to the wetting receptacle when in the operational position that application of the predetermined condition to the discharge outlet of the wetting fluid container when in the operational position enables the wetting fluid to be discharged into the wetting fluid receiving area for wetting of the hydrophilic urinary catheter. The problem of possible spillage of the wetting fluid is also alleviated in this case and manufacture, packaging and transport of the apparatus simplified.

15

20

25

In a preferred embodiment of the invention the wetting fluid is water or a saline solution.

30

In an embodiment of the invention hereinafter to be described the wetting fluid receiving area is an elongate pocket of length sufficient to accommodate at least the insertable length

of the hydrophilic urinary catheter and the wetting fluid container is adapted to contain sufficient wetting fluid to fill the pocket to a level for wetting at least the insertable length of the hydrophilic urinary catheter.

5 In a preferred embodiment of the invention hereinafter to be described the wetting receptacle is a urine collection bag, the elongate pocket forms the forward portion of the urine collection bag and presents an open rear end and a weakened closed forward end which is removable upon application of a predetermined pressure thereto thereby to enable a portion of the hydrophilic urinary catheter comprising at least the insertable length thereof
10 to be projected through the forward end of the pocket after wetting thereof for insertion into the urethra of a patient and the urine collection bag further comprises a urine collection chamber to the rear of the elongate pocket, the urine collection chamber having a forward end which is in fluid communication with the open rear end of the pocket and being adapted in use to collect urine transported rearwardly through the hydrophilic urinary catheter after
15 insertion thereof into the urethra of the patient.

A typical sterilising agent which could be used for sterilising the wetting apparatus of the invention is ethylene oxide. Moreover, the fluid in the fluid container would normally be sterile. For these reasons, the wetting fluid container is preferably made of a material which
20 is impermeable or substantially impermeable to ethylene oxide as well as the fluid contained therein. Non-limiting examples of materials satisfying this condition when the fluid is water or saline are aluminium foil, poly(vinylidene chloride) or a metallised film such as metallised poly(ethylene terephthalate).

25 In an embodiment of the invention hereinafter to be described the wetting fluid container is fully contained within the bounds of the wetting receptacle and may be permanently fixed to the inner surface of the wetting receptacle.

In an embodiment of the invention the wetting fluid container is an integrally formed
30 compartment of the wetting receptacle.

In an embodiment of the invention hereinafter to be described the wetting receptacle is formed of a flexible material and the discharge outlet is brought to the open position through application of a predetermined force to the wetting fluid container through the material of the wetting receptacle.

5

In an embodiment of the invention hereinafter to be described the wetting receptacle is provided with an inlet which is in fluid communication with the wetting fluid receiving area and the wetting fluid container is integrable with the wetting receptacle in the operational position by insertion of at least a forward portion thereof in the inlet, the forward portion of
10 the wetting fluid container presenting the discharge outlet.

In an embodiment of the invention hereinafter to be described the wetting fluid container is integrable with the wetting receptacle in the operational position through a friction fit between the wetting fluid container and the inlet of the wetting receptacle.

15

According to a third aspect of the invention there is provided a fluid container for use with a receptacle having an inlet and a fluid receiving area in fluid communication with the inlet, the fluid container comprising a forward portion which is adapted to be positioned in the inlet of the receptacle and comprises a discharge outlet movable on application of a
20 predetermined condition thereto from a closed position in which the fluid is retained in the fluid container to an open position in which the fluid is dischargeable forwardly from the forward portion of the fluid container, the predetermined condition able to be applied to the discharge outlet when the forward portion of the fluid container is positioned in the inlet to enable the fluid contained in the fluid container to be discharged into the fluid receiving area
25 of the receptacle. The fluid container therefore alleviates the problem of spillage on discharge of the contents into the fluid receiving area.

In an embodiment of the invention according to its third aspect hereinafter to be described the fluid container is for use with a receptacle whose fluid receiving area is adapted in use to
30 receive a hydrophilic urinary catheter and the fluid container contains a fluid which on discharge into the fluid receiving area wets the hydrophilic coating of the catheter.

In an embodiment of the invention hereinafter to be described the fluid container comprises predetermined condition applying means for applying the predetermined condition to the discharge outlet to bring the discharge outlet to the open position.

5

In an embodiment of the invention hereinafter to be described the forward portion of the fluid container is positioned in the inlet of the receptacle when the fluid container is in the operational position, the fluid container comprises a rearward portion which in the operational position of the fluid container projects from the inlet of the receptacle and the rearward portion comprises at least a part of the predetermined condition applying means.

10

In an embodiment of the invention hereinafter to be described the discharge outlet comprises an area of weakness in the material of the forward portion of the fluid container which on application of a predetermined force thereto is brought to the open position.

15

In an embodiment of the invention hereinafter to be described the at least a part of the predetermined condition applying means comprised of the rearward portion of the fluid container is a tab which on application of a predetermined pulling force thereto causes the predetermined force to be applied to the area of weakness in the material of the forward portion of the fluid container.

20

In an embodiment of the invention hereinafter to be described the area of weakness in the material of the forward portion of the fluid container is a tear line which is torn on application of the predetermined pulling force to the tab. The predetermined condition applying means further comprises holding means for holding the fluid container in the operational position against the action of the predetermined pulling force applied to the tab.

25

In an embodiment of the invention hereinafter to be described the receptacle is of a flexible material and the holding means is provided on the forward portion to be gripped by a user through the material of the receptacle when the fluid container is in the operational position.

30

In an embodiment of the invention hereinafter to be described the forward portion of the fluid container presents a forward edge, the tear line extends rearwardly from the forward edge, the tab is a first tab which extends rearwardly from the forward edge of the forward portion on a first side of the tear line and is of such dimensions that when the fluid container is in the operational position the first tab projects from the inlet of the receptacle, the holding means for holding the fluid container in the operational position against the action of the pulling force applied to the first tab is a second tab which extends forwardly from the forward edge on a second opposite side of the tear line and application of a predetermined rearward pulling force on the first tab relative to the second tab causes the tear line to tear and the fluid to be dischargeable from the fluid container into the fluid receiving area of the receptacle.

In embodiments of the invention hereinafter to be described the fluid container takes the form of a sachet.

In an embodiment of the invention according to its third aspect hereinafter to be described the fluid container is adapted to be integrated with the receptacle by friction fit in the inlet of the receptacle to maintain the fluid container in the operational position. An integrated unit is thus obtained having the benefits of the apparatus according to the first and second aspects of the invention.

In an embodiment of the invention according to its third aspect the fluid container contains water or saline and is made of aluminium foil, poly(vinylidene chloride) or a metallised film such as metallised poly(ethylene terephthalate).

The present invention has the advantage of providing a safe, compact, sterile and disposable wetting apparatus for a hydrophilic urinary catheter which is easy to handle. This is due to the provision of a wetting fluid container component part which is adapted to cooperate with a wetting receptacle component part of the apparatus so as to be able to release its contents into the wetting receptacle to wet a hydrophilic urinary catheter placed therein under clean conditions, that is to say, without the need for touching of the catheter, fluid or

inner surface of the wetting receptacle thereby avoiding or alleviating the risk of introducing contaminants.

By way of example embodiments of the invention will now be described with reference to the accompanying drawings in which:-

Fig. 1 shows a wetting apparatus according to a first embodiment of the invention comprising a urine collection bag and a wetting fluid container integrated therewith;

Fig. 2 shows a wetting apparatus according to a second embodiment of the invention comprising a urine collection bag and an unopened wetting fluid sachet in accordance with the invention integrated therewith in an operational position in the inlet of the urine collection bag;

Fig. 3 is an exploded view of the unopened sachet of the wetting apparatus shown in Fig. 2 in the operational position in the inlet of the urine collection bag;

Fig. 4 is a front view of the unopened sachet of the wetting apparatus shown in Fig. 2 in an extended configuration prior to insertion thereof into the inlet of the urine collection bag to the operational position;

Fig. 5 is a side view of the unopened sachet shown in Fig. 4;

Fig. 6 is a perspective view of the unopened sachet of the wetting apparatus shown in Fig. 2 in a retracted configuration ready for insertion into the inlet of the urine collection bag to the operational position;

Fig. 7 corresponds to Fig. 2 but with the wetting fluid sachet having been opened; and

Fig. 8 corresponds to Fig. 3 but with the wetting fluid sachet having been opened.

Referring first to Fig. 1, there is shown a wetting apparatus 10 according to the invention comprising a urine collection bag 1 of a transparent flexible plastics material. The bag 1 presents at the forward end thereof an elongate pocket 2 of depth sufficient to receive at least the insertable length of a hydrophilic urinary catheter 3. The urine collection bag 1 further defines to the rear of the pocket 2 a urine collection chamber 12 which is in fluid communication with the pocket 2. Further rearwardly is an inlet 14 to the urine collection bag 1 through which the hydrophilic urinary catheter 3 is able to be introduced into the bag 1.

As can be seen, the catheter 3 comprises a flared rearward portion 16 and an elongate shaft 18 which extends forwardly from the rearward portion 16 and terminates in a rounded tip 4 at the forward end thereof. The catheter 3 is provided with a lumen (not shown) which extends from an open end in the rearward portion 16 to a drainage aperture 5 in the tip 4.

A container in the form of a sachet 6 is secured to the inner surface of the urine bag 1. The sachet 6 contains sterile water or saline or other fluid suitable for wetting the hydrophilic urinary catheter 3 and is pierceable or otherwise openable, for example by applying a hand pressure, so as to release substantially all of the water or saline contained therein into the pocket 2 immediately prior to use of the catheter 3.

Typically, the urine collection bag 1 with integrated sachet 6 and, where pre-packaged therewith, the catheter 3 will be sterilised using ethylene oxide. Since the sachet 6 contains sterile water or saline there is no need for sterilising the contents of the sachet 6.

Accordingly, the material of the sachet 6 is preferably impermeable to ethylene oxide and water. Non-limiting examples of materials meeting these requirements are poly(vinylidene chloride) (PVDC), aluminium foil laminates and metallised films, for example metallised poly(ethylene terephthalate). Other sterilisation processes could of course be used instead, for example by irradiation in which case the fluid in the sachet 6 could be sterilised in situ at the same time as the rest of the components of the apparatus 10.

The volume of the sachet 6 is sufficient to release such an amount of water or saline into the pocket 2 to enable wetting of the insertable length of the catheter 3 immediately prior to use. By "insertable length" is meant at least that length of the elongate shaft 18 which is coated with a hydrophilic material, for example PVP, and inserted into the urethra of the patient. Typically, this will be 80-140mm for a female patient and 200-350mm for a male patient.

The holding time of the catheter 3 in the pocket 2 may vary within a broad range but will typically amount to at least 30 seconds.

10

The location of the sachet 6 inside the bag 1 is not critical as long as the sachet 6 releases its contents into the pocket 2. It is preferred, though, that the sachet 6 be disposed as close to the open end of the pocket 2 as possible. In this embodiment the sachet 6 is permanently fixed in position in the urine collection bag 1, for example by adhesion to the bag 1. It will be appreciated, however, that the sachet 6 could in fact be freely movable in the bag 1. The fundamental point is that the sachet 6 is within the bounds of the bag 1 so that the two components form an integrated unit.

In use, the catheter 3 is introduced into the bag 1 through the inlet 14 and the elongate shaft 18 manoeuvred into the pocket 2 as shown. The inlet 14 is then sealed, for example by tying a knot in the material defining the inlet 14 or by clamping the inlet 14 with a clamp. The sachet 6 is then opened, for example by applying a pressure thereto through the material of the bag 1, to release the wetting fluid into the pocket 2 and the catheter 3 left to soak for a predetermined duration in the wetting fluid to wet the hydrophilic outer surface thereof.

25

Alternately, the bag 1 may be provided with a closed end in place of the inlet with the catheter 3 pre-packaged inside the bag 1. An inlet 14 is preferred, though, where ethylene oxide is the sterilising agent as this provides a pathway for the ethylene oxide to enter and exit the inside of the bag 1.

30

After wetting of the catheter 3 for the predetermined duration, the bag 1 is turned upside down and the forwardmost portion of the pocket 2 torn off. The elongate shaft 18 of the catheter 3 is then manoeuvred through the opening in the forward end of the pocket 2 and into the urethra of the patient until the flared rearward portion 16 forms a mechanical seal connection with the opening. There is therefore no need to directly handle the catheter 3 for insertion thereof into the urethra which is to advantage as the outer surface of the catheter 3 will be slippery due to the wetting procedure and therefore difficult to grip and furthermore because the possibility of contamination of the catheter 3 at this stage is avoided.

Urine in the bladder of the patient is transported rearwardly through the lumen of the catheter 3 into the urine collection chamber 12. The catheter 3 is manoeuvred back inside the bounds of the bag 1 and the open end of the pocket 2 closed off for example by tying a knot with the material defining the pocket 2 or clamping the pocket 2 with a clamp. An opening can then be made in the urine collection chamber 12 for the collected urine to be poured away after which the bag 1 can be disposed of.

Turning now to Figs 2 and 3 of the drawings, there is shown an alternative wetting apparatus 110 according to the present invention. The wetting apparatus 110 comprises a urine collection bag 101 of a flexible transparent plastics material which corresponds to the urine collection bag 1 of the wetting apparatus 10 hereinbefore described with reference to Fig. 1 of the drawings. That is to say, the urine collection bag 101 has a downwardly extending elongate pocket 102 at the forward end, a urine collection chamber 112 rearwardly of and in fluid communication with the elongate pocket 102 and an inlet 114 to the bag 101 spaced further rearwardly.

Again as in the wetting apparatus 10 hereinbefore described with reference to Fig. 1, a hydrophilic urinary catheter 103 having a flared rearward portion 116, an elongate shaft 118 projecting forwardly from the rearward portion 116 and an open-ended lumen (not shown) which extends from the rear end of the rearward portion 116 to a drainage aperture 105 in the rounded tip 104 at the forward end of the catheter 103 is able to be inserted into the

urine collection bag 101 through the inlet 114 such that preferably at least the insertable length of the catheter 103 is received in the pocket 102.

As can be seen more particularly by reference to Fig. 3, a wetting fluid containing sachet 106 is inserted into the inlet 114 to an operational position in which it is held in place by a friction fit. The sachet 106 has a forward portion 120 which in the operational position of the sachet 106 projects forwardly into the inlet 114 and a rearward portion 122 which in the operational position projects rearwardly out of the inlet 114.

The sachet 106 is preferably made of aluminium foil, particularly when ethylene oxide is the sterilising agent for the apparatus 110 and the sachet contains sterile water or saline solution. Where ethylene oxide is the sterilising agent for the apparatus 110 the fit of the sachet 106 in the inlet 114 is not so tight as to prevent ethylene oxide from entering and exiting the inside of the bag 101 and sterilising the inner surface of the bag 101 and outer surfaces of the sachet 106 and catheter 103. The wetting fluid is retained in the sachet 106 by peripheral sealing of the sachet 106 as shown.

Referring now to Figs 4 and 5, the forward portion 120 of the sachet 106 presents a forward edge 124. Extending rearwardly from the forward edge 124 is a tear line 126. Projecting forwardly from the forward edge 124 of the sachet 106 to one side of the tear line 126 is a first tab 128. On the other side of the tear line 126 there is provided an elongate second tab 130 shown here in an extended position in which the second tab 130 projects forwardly from the forward edge 124.

As shown in Fig. 6, the elongate second tab 130 is movable about the forward edge 124 back on its self from the extended position shown in Figs 4 and 5 to a retracted position in which the second tab 130 extends rearwardly from the forward edge 124. When the second tab 130 is in the retracted position the sachet 106 is inserted into the inlet 114 to the operational position shown in Figs 2 and 3.

Returning now to Figs 2 and 3, it can be seen that the dimensions of the second tab 130 are such that when the sachet 106 is in the operational position a pulling portion 132 of the second tab 130 projects rearwardly from the inlet 114 of the urine collection bag 101 and forms a part of the rearward portion 122 of the sachet 106.

5 In Figs 7 and 8 there is shown the operation of the sachet 106 to release the contents of the sachet 106 into the pocket 102 to wet the hydrophilic outer coating of the catheter 103. The user grips the first tab 128 through the flexible transparent plastics material of the bag 101 and then pulls rearwardly on the pulling portion 132 of the second tab 130 which
10 projects from the inlet 114 to cause the tear line 126 to be torn and the wetting fluid to be released into the pocket 102 to wet the catheter 103. Preferably, the sachet 106 contains sufficient wetting fluid for the pocket 102 to be filled to a level which results in the insertable length of the catheter 103 being wetted .

15 After release of the wetting fluid into the pocket 102 the sachet 106 is removed from the bag 101 and disposed of. The bag 101 and catheter 103 are then utilised in the manner hereinabove described for the wetting apparatus 10 shown in Fig. 1.

If need be, the bag 101 can be a closed bag with the sachet 106 and catheter 103 pre-
20 packaged within the bag 101. In this instance, the construction of the bag 101 is such that the sachet 106 can be opened in the aforementioned manner through the material of the bag 101.

The wetting apparatus 110 described hereinabove with reference to Figs 2 to 8 has the
25 advantage of *inter alia* (i) being environmentally friendly in the sense that where the sachet 106 is made of Al foil the sachet is able to be disposed of separately from the bag 101 thus facilitating recycling of the Al foil; and (ii) having a sachet 106 which can better withstand the cyclical pressures which are typically exerted on wetting apparatus when packaged and subjected to a sterilising process as a consequence of the sachet 106 not having to be
30 opened through application of a direct pressure thereto through the material of the bag 101

in which case a significantly weakened sachet edge would be required as a high pressure could not be applied through the bag 101 without damaging the bag 101.

In the exemplary embodiments hereinabove described with reference to the Figures of drawings the supply of wetting fluid for wetting of the hydrophilic urinary catheter takes the form of a separate sachet integrated into the wetting receptacle. It will be appreciated by those versed in the art that the supply could also take the form of an integrally formed chamber in the material of the wetting receptacle without departing from the spirit of the invention.

Claims:

1. A wetting apparatus for wetting a hydrophilic urinary catheter comprising a wetting receptacle which defines a wetting fluid receiving area for receiving a hydrophilic urinary catheter and a hydrophilic urinary catheter wetting fluid container having a discharge outlet movable from a closed position to an open position on application of a predetermined condition thereto to enable the wetting fluid to be discharged from the wetting fluid container **characterised in that** the wetting fluid container is integrated with the wetting receptacle in an operational position in which at least the discharge outlet of the wetting fluid container is disposed within the bounds of the wetting receptacle, the wetting receptacle being so constructed and the wetting fluid container being so disposed relative to the wetting receptacle when in the operational position that application of the predetermined condition to the discharge outlet of the wetting fluid container when in the operational position enables the wetting fluid to be discharged into the wetting fluid receiving area for wetting of the hydrophilic urinary catheter **and that** the insertable length or substantially the insertable length of the hydrophilic urinary catheter is wetted by the wetting fluid discharged into the wetting fluid receiving area.

2. A wetting apparatus for wetting a hydrophilic urinary catheter comprising a wetting receptacle which defines a wetting fluid receiving area for receiving a hydrophilic urinary catheter and a hydrophilic urinary catheter wetting fluid container having a discharge outlet movable from a closed position to an open position on application of a predetermined condition thereto to enable the wetting fluid to be discharged from the wetting fluid container **characterised in that** the wetting fluid container is integrable with the wetting receptacle in an operational position in which at least the discharge outlet of the wetting fluid container is disposed within the bounds of the wetting receptacle, the wetting receptacle being so constructed and the wetting fluid container being so disposed relative to the wetting receptacle when in the operational position that application of the predetermined condition to the discharge outlet of the wetting fluid container when in the

operational position enables the wetting fluid to be discharged into the wetting fluid receiving area for wetting of the hydrophilic urinary catheter.

3. A wetting apparatus according to claim 1 or 2, **characterised in that** the wetting
5 fluid is water or a saline solution.

4. A wetting apparatus according to claim 1, 2 or 3, **characterised in that** the
wetting fluid receiving area is an elongate pocket of length sufficient to accommodate at
least the insertable length of the hydrophilic urinary catheter **and that** the wetting fluid
10 container is adapted to contain sufficient wetting fluid to fill the pocket to a level for
wetting at least the insertable length of the hydrophilic urinary catheter.

5. A wetting apparatus according to claim 4, **characterised in that** the wetting
receptacle is a urine collection bag, **that** the elongate pocket forms the forward portion of
15 the urine collection bag and presents an open rear end and a weakened closed forward end
which is removable upon application of a predetermined pressure thereto thereby to enable
a portion of the hydrophilic urinary catheter comprising at least the insertable length thereof
to be projected through the forward end of the pocket after wetting thereof for insertion
into the urethra of a patient, **and that** the urine collection bag further comprises a urine
20 collection chamber to the rear of the elongate pocket, the urine collection chamber having a
forward end which is in fluid communication with the open rear end of the pocket and being
adapted in use to collect urine transported rearwardly through the hydrophilic urinary
catheter after insertion thereof into the urethra of the patient.

25 6. A wetting apparatus according to any one of the preceding claims, **characterised
in that** the wetting fluid container contains sterile water or saline solution and is made of a
material which is impermeable to ethylene oxide and water or saline solution.

7. A wetting apparatus according to any one of the preceding claims, **characterised in that** the wetting fluid container is made of aluminium foil, poly(vinylidene chloride) or a metallised film such as metallised poly(ethylene terephthalate).

5 8. A wetting apparatus according to any one of the preceding claims, **characterised in that** the wetting fluid container is fully contained within the bounds of the wetting receptacle.

9. A wetting apparatus according to claim 8, **characterised in that** the wetting fluid
10 container is permanently fixed to the inner surface of the wetting receptacle.

10. A wetting apparatus according to claim 8, **characterised in that** the wetting fluid container is an integrally formed compartment of the wetting receptacle.

15 11. A wetting apparatus according to claim 8, 9 or 10, **characterised in that** the wetting receptacle is formed of a flexible material **and that** the discharge outlet is brought to the open position through application of a predetermined force to the wetting fluid container through the material of the wetting receptacle.

20 12. A wetting apparatus according to any one of claims 1 to 7, **characterised in that** the wetting receptacle is provided with an inlet which is in fluid communication with the wetting fluid receiving area **and that** the wetting fluid container is integrable with the wetting receptacle in the operational position by insertion of at least a forward portion thereof in the inlet, the forward portion of the wetting fluid container presenting the
25 discharge outlet.

13. A wetting apparatus according to claim 12, **characterised in that** the wetting fluid container is integrable with the wetting receptacle in the operational position through a friction fit between the wetting fluid container and the inlet of the wetting receptacle.

14. A wetting apparatus according to claim 12 or 13, characterised in that the wetting fluid container comprises predetermined condition applying means for applying the predetermined condition to the discharge outlet to bring the discharge outlet to the open position.

5

15. A wetting apparatus according to claim 14, characterised in that the forward portion of the wetting fluid container is positioned in the inlet of the wetting receptacle when the wetting fluid container is in the operational position, that the wetting fluid container comprises a rearward portion which in the operational position of the wetting
10 fluid container projects from the inlet of the wetting receptacle and that the rearward portion comprises at least a part of the predetermined condition applying means.

16. A wetting apparatus according to any one of claims 12 to 15, characterised in that the discharge outlet comprises an area of weakness in the material of the forward portion of
15 the wetting fluid container which on application of a predetermined force thereto is brought to the open position.

17. A wetting apparatus according to claim 16 as appendant to claim 15, characterised in that the at least a part of the predetermined condition applying means comprised of the
20 rearward portion of the wetting fluid container is a tab which on application of a predetermined pulling force thereto causes the predetermined force to be applied to the area of weakness in the material of the forward portion of the wetting fluid container.

18. A wetting apparatus according to claim 17, characterised in that the area of
25 weakness in the material of the forward portion of the wetting fluid container is a tear line which is torn on application of the predetermined pulling force to the tab.

19. A wetting apparatus according to claim 17 or 18, characterised in that the predetermined condition applying means further comprises holding means for holding the

wetting fluid container in the operational position against the action of the predetermined pulling force applied to the tab.

20. A wetting apparatus according to claim 19, **characterised in that** the wetting
5 receptacle is of a flexible material **and that** the holding means is provided on the forward portion to be gripped by a user through the material of the wetting receptacle when the wetting fluid container is in the operational position.

21. A wetting apparatus according to claim 20, **characterised in that** the forward
10 portion of the wetting fluid container presents a forward edge, **that** the tear line extends rearwardly from the forward edge, **that** the tab is a first tab which extends rearwardly from the forward edge of the forward portion on a first side of the tear line and is of such dimensions that when the wetting fluid container is in the operational position the first tab projects from the inlet of the wetting receptacle, **that** the holding means for holding the
15 wetting fluid container in the operational position against the action of the pulling force applied to the first tab is a second tab which extends forwardly from the forward edge on a second opposite side of the tear line **and that** application of a predetermined rearward pulling force on the first tab relative to the second tab causes the tear line to tear and the wetting fluid to be dischargeable from the wetting fluid container into the wetting fluid
20 receiving area of the wetting receptacle.

22. A wetting apparatus according to any one of claims 1 to 9, claim 11 when
25 appendant to claim 8 or 9, or any one of claims 12 to 21, **characterised in that** the wetting fluid container takes the form of a sachet.

23. A fluid container for use with a receptacle having an inlet and a fluid receiving area
in fluid communication with the inlet, the fluid container comprising a forward portion
which is adapted to be positioned in the inlet of the receptacle and comprises a discharge
outlet movable on application of a predetermined condition thereto from a closed position in
30 which the fluid is retained in the fluid container to an open position in which the fluid is

dischargeable forwardly from the forward portion of the fluid container, the predetermined condition able to be applied to the discharge outlet when the forward portion of the fluid container is positioned in the inlet to enable the fluid contained in the fluid container to be discharged into the fluid receiving area of the receptacle.

3

24. A wetting fluid container for use with a wetting receptacle having an inlet and a wetting fluid receiving area for receiving a hydrophilic urinary catheter and in fluid communication with the inlet, the wetting fluid container comprising a forward portion which is adapted to be positioned in the inlet of the receptacle and comprises a discharge outlet movable on application of a predetermined condition thereto from a closed position in which the wetting fluid is retained in the wetting fluid container to an open position in which the wetting fluid is dischargeable forwardly from the forward portion of the wetting fluid container, the predetermined condition able to be applied to the discharge outlet when the forward portion of the wetting fluid container is positioned in the inlet to enable the wetting fluid contained in the wetting fluid container to be discharged into the wetting fluid receiving area of the receptacle.

10

15

20

25. A fluid container according to claim 23 or 24, characterised in that the fluid container comprises predetermined condition applying means for applying the predetermined condition to the discharge outlet to bring the discharge outlet to the open position.

25

26. A fluid container according to claim 25, characterised in that when the forward portion of the fluid container is positioned in the inlet of the receptacle the fluid container is in an operational position, that the fluid container comprises a rearward portion which in the operational position of the fluid container projects from the inlet of the receptacle and that the rearward portion comprises at least a part of the predetermined condition applying means.

27. A fluid container according to any one of claims 23 to 26, **characterised in that** the discharge outlet comprises an area of weakness in the material of the forward portion of the fluid container which on application of a predetermined force thereto is brought to the open position.

28. A fluid container according to claim 27 as appendant to claim 26, **characterised in that** the at least a part of the predetermined condition applying means comprised of the rearward portion of the fluid container is a tab which on application of a predetermined pulling force thereto causes the predetermined force to be applied to the area of weakness in the material of the forward portion of the fluid container.

29. A fluid container according to claim 28, **characterised in that** the area of weakness in the material of the forward portion of the fluid container is a tear line which is torn on application of the predetermined pulling force to the tab.

30. A fluid container according to claim 28 or 29, **characterised in that** the predetermined condition applying means further comprises holding means for holding the fluid container in the operational position against the action of the predetermined pulling force applied to the tab.

31. A fluid container according to claim 30, **characterised in that** the receptacle is of a flexible material **and that** the holding means is provided on the forward portion to be gripped by a user through the material of the receptacle when the fluid container is in the operational position.

32. A fluid container according to claim 31, **characterised in that** the forward portion of the fluid container presents a forward edge, **that** the tear line extends rearwardly from the forward edge, **that** the tab is a first tab which extends rearwardly from the forward edge of the forward portion on a first side of the tear line and is of such dimensions that when the fluid container is in the operational position the first tab projects from the inlet of the

receptacle, **that** the holding means for holding the fluid container in the operational position against the action of the pulling force applied to the first tab is a second tab which extends forwardly from the forward edge to a second opposite side of the tear line **and that** application of a predetermined rearward pulling force on the first tab relative to the second tab causes the tear line to tear and the fluid to be dischargeable from the fluid container into the fluid receiving area of the receptacle.

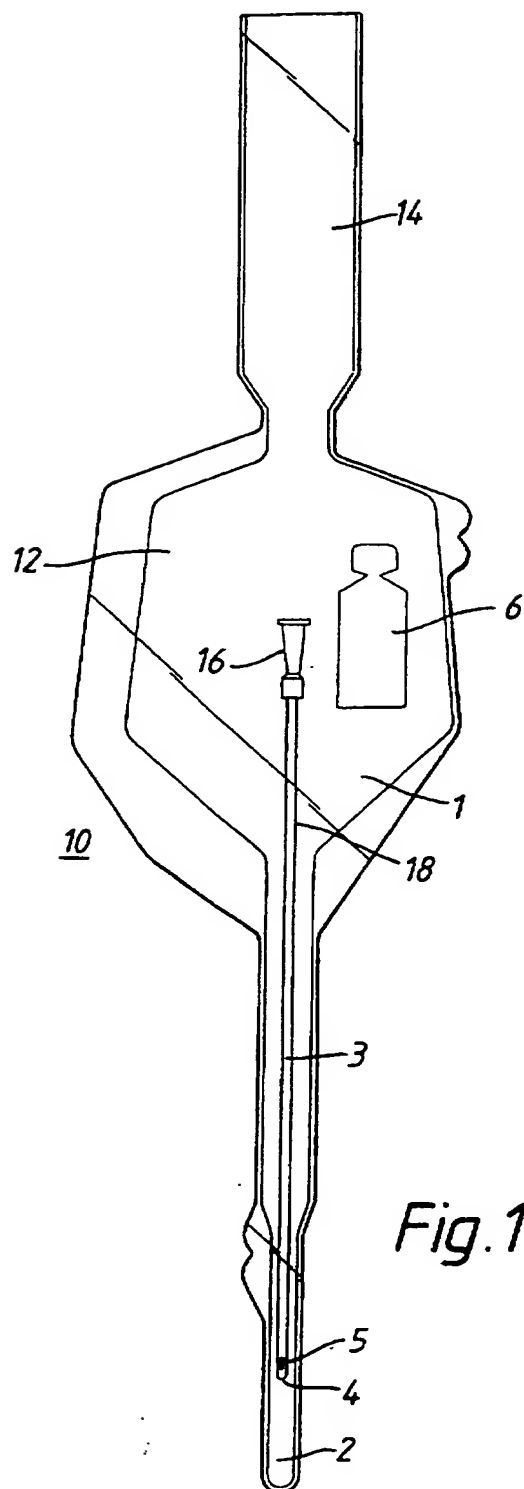
33. A fluid container according to claim 26, claim 27 as appendant to claim 26 or any one of claims 28 to 32, **characterised in that** the fluid container is adapted to be friction fitted in the inlet of the receptacle to maintain the fluid container in the operational position.

34. A fluid container according to any one of claims 23 to 33, **characterised in that** the fluid container is a sachet.

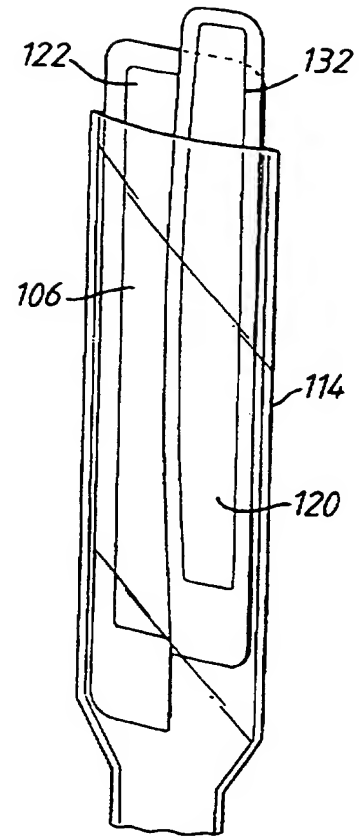
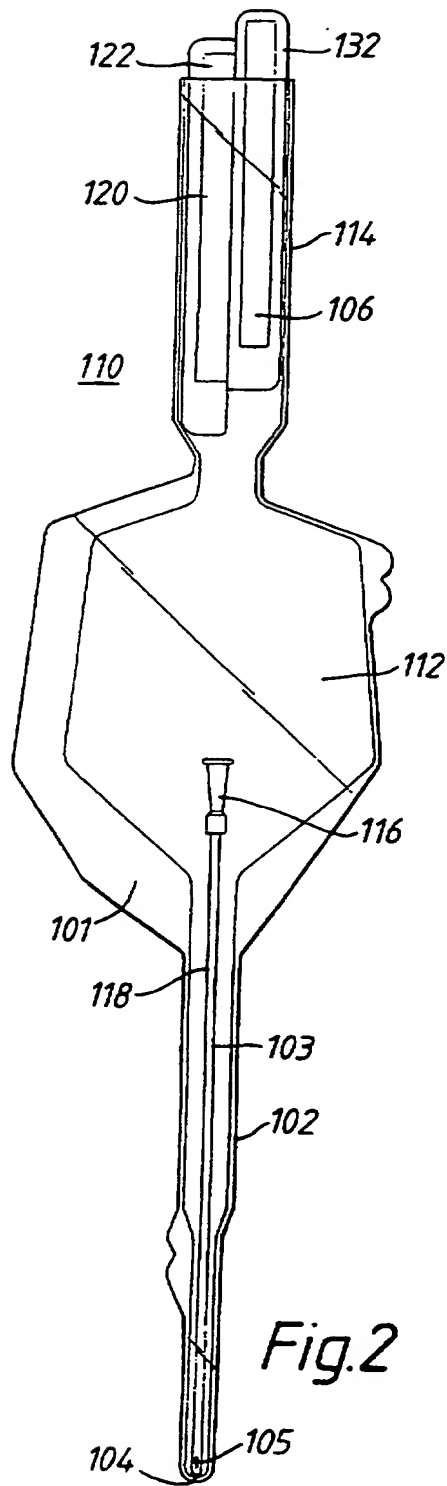
35. A fluid container according to any one of claims 23 to 34, **characterised in that** the fluid container is made of aluminium foil, poly(vinylidene chloride) or a metallised film such as metallised poly(ethylene terephthalate).

36. A fluid container according to any one of claims 23 to 35, **characterised in that** the fluid container contains water or a saline solution.

1/4



2/4



3/4

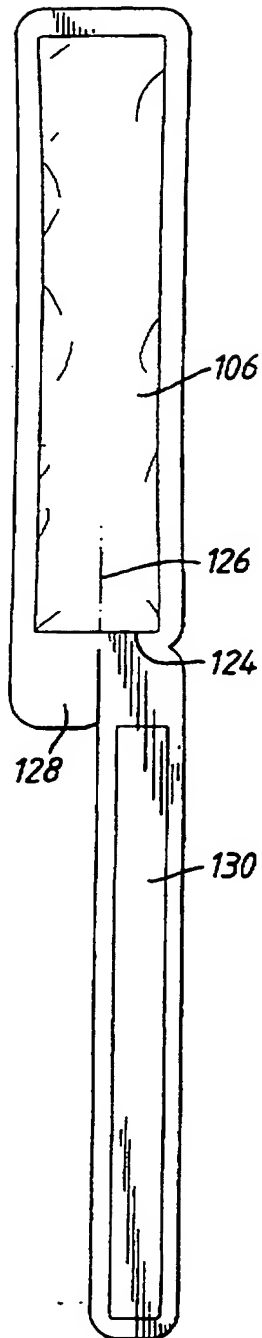


Fig. 4

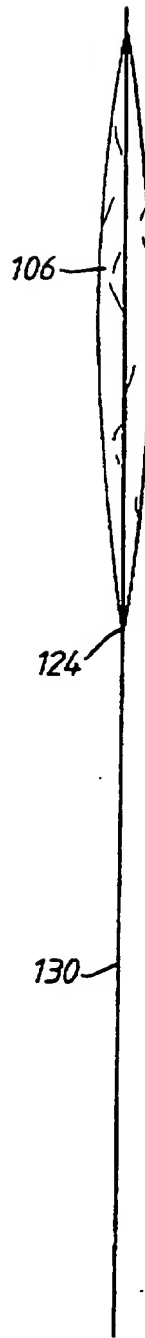


Fig. 5

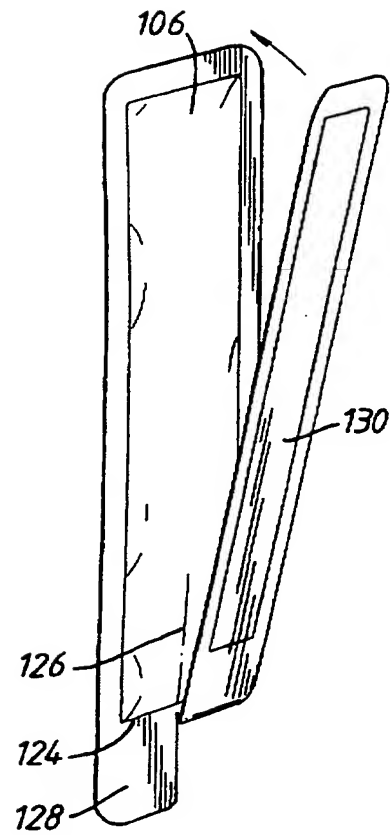
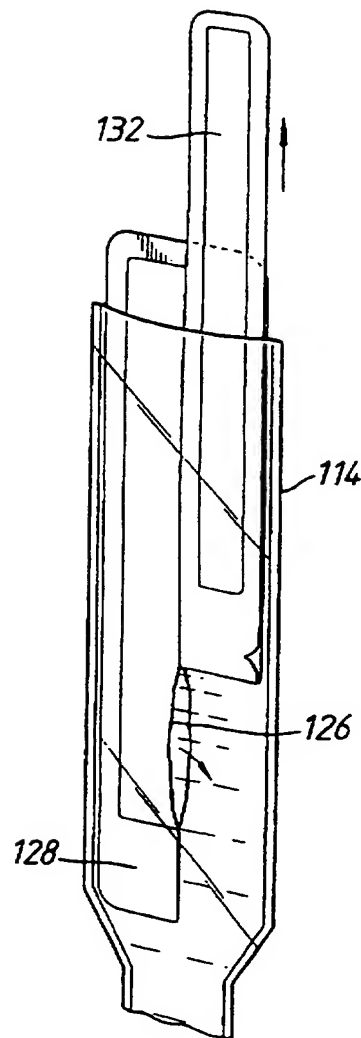
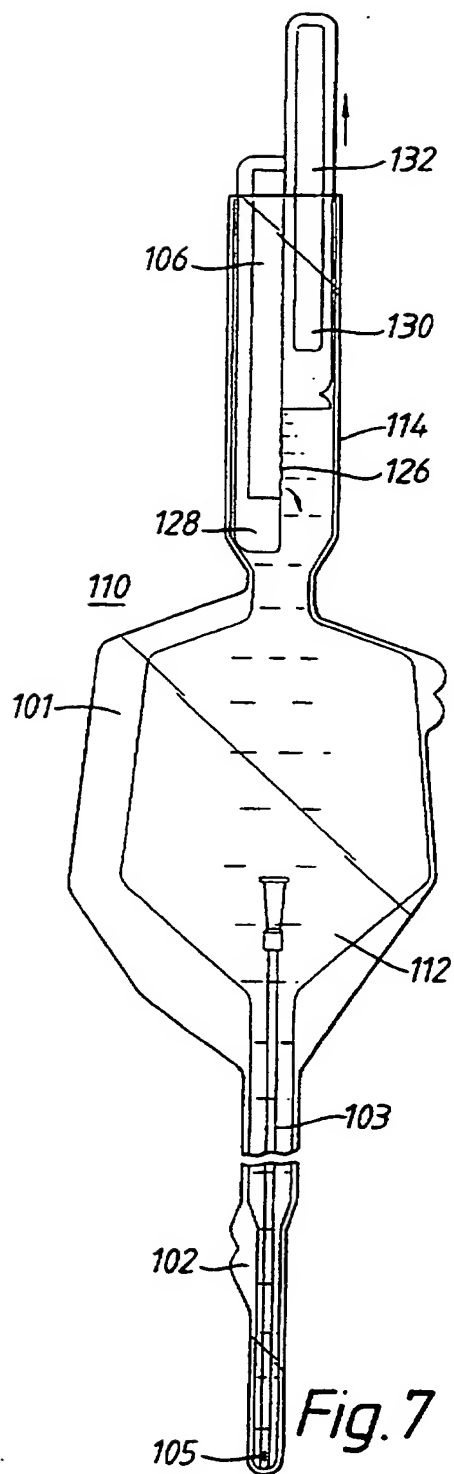


Fig. 6

4/4



INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 97/00096

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61M 25/01, A61F 5/44

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61M, A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

WPIL

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	GB 2284764 A (MMG(EUROPE)LTD.), 21 June 1995 (21.06.95), page 3, line 35 - page 4, line 2; page 6, line 18 - line 32, figure 1 --	1-3,6-36
X	US 3967728 A (R.L.GORDON ET AL.), 6 July 1976 (06.07.76), column 3, line 20 - line 35, figures 1, 5 --	1-4,6-36
A	US 2856932 A (J.J.GRIFFITTS), 21 October 1958 (21.10.58), column 3, line 16 - line 47, figures 1, 4 --	4,5

☒ Further documents are listed in the continuation of Box C.☒ See patent family annex.

* Special categories of cited documents:

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

15 May 1997

Date of mailing of the international search report

22.05.97

Name and mailing address of the ISA/

Swedish Patent Office

Box 5055, S-102 42 STOCKHOLM

Facsimile No. +46 8 666 02 86

Authorized officer

Eva Selin

Telephone No. +46 8 782 25 00

INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 97/00096

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 3648704 A (F.E.JACKSON), 14 March 1972 (14.03.72), column 2, line 35 - column 3, line 73, figures 1-3 -----	1-36

INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE97/00096

Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claims Nos.: 23
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

Claim 23 has been searched together with the information in claims 1 or 2. Just the information in claim 23 does not solve the posed problem.

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

02/04/97

International application No.

PCT/SE 97/00096

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
GB 2284764 A	21/06/95	NONE	
US 3967728 A	06/07/76	GB 1465544 A	23/02/77
US 2856932 A	21/10/58	NONE	
US 3648704 A	14/03/72	NONE	